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nanotherapeutics

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510(k) SUMMARY OF SAFETY & EFFECTIVENESS

NanoFUSE® DBM

Date: January 27, 2012

Submitted by: Nanotherapeutics, Inc.
13859 Progress Blvd., Suite 300
Alachua, FL 32615

Representative: Gregg Ritter, MS, RAC, CTBS
Regulatory Affairs Manager
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Proprietary Name: NanoFUSE® DBM

Common Name: Bone Void Filler, Bone Graft Substitute

Classification Name: Filler, Calcium Sulfate Preformed Pellets, 21 CFR § 888.3045

Classification Codes: MQV, MBP - Class II

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(k) Number
Origen™ DBM with Bioactive Glass (NanoFUSE® DBM)	Nanotherapeutics	K062459, K110976

Description: NanoFUSE® DBM is a malleable, putty-like, bone-void filler. The product is comprised of human demineralized bone matrix (DBM) and synthetic calcium phosphor-silicate particulate material particles (45s5 bioactive glass), both coated with gelatin derived from porcine skin. These coated particles are packaged dry in a single use, polypropylene syringe (20 cc or 3 cc), double-wrapped in peel-back pouches, and final packaged in a dust cover paperboard carton. The 20 cc syringe will be filled with either of two different fill quantities of dry powder, identified as 10 cc or 5 cc final product volume. The 3 cc syringe will be filled with dry powder, identified as 2 cc final product volume. NanoFUSE® DBM is intended for single patient use only.

At point of use, the surgeon will reconstitute the product with an appropriate sterile solution of his/her choice (sterile saline, water for injection). The coated particles rehydrate in less than 30 seconds and do not require mixing to form a uniform paste or putty. The material is then gently extruded by the surgeon into the appropriate bone voids. NanoFUSE® DBM is progressively resorbed and replaced by host bone during the osteo-remodeling process.

Indications for Use: NanoFUSE® DBM is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. It is indicated to be placed into bony voids or gaps of

the skeletal structure (e.g., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. The product provides a bone graft substitute that remodels into the recipient's skeletal system.

Technological Characteristics:

The applicant version of NanoFUSE® DBM is identical to the currently legally marketed medical device NanoFUSE® DBM, also manufactured by Nanotherapeutics, Inc. with respect to materials, design, and intended use. The applicant version is comprised of human demineralized bone matrix (DBM) and synthetic calcium phosphor-silicate particulate material particles (45s5 bioactive glass), both coated with gelatin derived from porcine skin. It is provided dry and is reconstituted at the point of use into a paste-like, malleable form that can be molded or manipulated into bony defects.

NanoFUSE® DBM is reconstituted by the addition of fluid and waiting 30 seconds before expelling the contents from the syringe. At 30 seconds, the product extrudes as a very fluid paste and, with time, the gelatin carrier absorbs the fluid, becomes progressively thicker, and eventually sets in a rubbery mass.

Currently, each lot of DBM used in manufacturing the predicate Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is screened for osteoinductivity in an *in vitro* bioassay. Each lot of DBM used in manufacturing the applicant version of NanoFUSE® DBM will be screened for osteoinductivity with either the *in vitro* bioassay originally submitted or the *in vivo* athymic rat model herein submitted.

The scientific technology of NanoFUSE® DBM applicant product, using *in vivo* testing for osteoinductivity, is identical to the technology used in the FDA cleared predicates. (K062459, K110976)

Comparison Feature	NanoFUSE® DBM - Predicate	NanoFUSE® DBM - Applicant
Form	Syringe	Same
Materials of Construction	DBM, bioactive glass, gelatin	Same
Comparable Sizes	Yes	Yes
Osteoinductivity Assay	Cell bioassay	*in vivo* athymic rat implant or cell bioassay
Sterility	Yes – Radiation	Same

Osteoinductivity Potential:	Each lot of DBM incorporated into NanoFUSE® DBM is evaluated for osteoinductive (OI) potential using an *in vitro* bioassay or *in vivo* athymic rat model. Results from this bioassay were correlated to the athymic rat model. Testing each lot of DBM with this cell bioassay or athymic rat model assures that only DBM with osteoinductive potential is used in NanoFUSE® DBM. The combination of DBM, bioactive glass, and porcine gelatin has not been evaluated for osteoinductivity; therefore, it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. It is unknown how the OI of the DBM component, measured via the *in vitro* bioassay or athymic rat model, will correlate with human clinical performance of NanoFUSE® DBM.
Viral Clearance and Inactivation:	The change in osteoinductivity potential testing for the DBM does not alter the fundamental scientific technology of the device and it does not have an effect on the viral clearance and inactivation of the device. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes has previously been evaluated. The viral inactivation testing demonstrated that suitable viral inactivation potential was obtained by the processing method for a wide spectrum of potential human viruses.
Safety and Effectiveness:	The change in osteoinductivity potential testing for the DBM does not alter the fundamental scientific technology of the device and it does not have an effect on the biocompatibility of the device. Biocompatibility testing, pre-clinical animal testing and *in vitro* bench testing has previously been conducted to evaluate the biological safety and performance characteristics of NanoFUSE® DBM according to ISO 10993.
Substantial Equivalence:	The change in osteoinductivity potential testing for the DBM does not alter the fundamental scientific technology of the device. Based on the testing provided, the submitted change does not have an effect on the safety or effectiveness of the device. Therefore, the applicant version of NanoFUSE® DBM is substantially equivalent to the currently cleared version of Origen DBM® with Bioactive Glass (NanoFUSE® DBM).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nanotherapeutics, Incorporated
% Mr. Gregg Ritter, MS, RAC, CTBS
Regulatory Affairs Manager
13859 Progress Boulevard, Suite 300
Alachua, Florida 32615

APR - 6 2012

Re: K120279
Trade/Device Name: NanoFUSE® DBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: January 27, 2012
Received: January 30, 2012

Dear Mr. Ritter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

nanotherapeutics

INDICATIONS FOR USE

510(k) Number (if known): K120279

Device Name: NanoFUSE® DBM

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120279